REACTICE REACTIVATING ICE BAUME- menthol cream Rejuventus, Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Reactice Reactivating Ice Baume

Active ingredients Purpose

Menthol (5%) External Analgesic

Uses

For temporary relief of minor aches and pains of muscles such as: simple backache, lumbago, arthritis, neuralgia, strains, bruises, strains, bruises, and sprains

Keep out of reach of children

Consult a doctor and discontinue use if conditions worsen or persist for more than 7 days.

For External use only. When using this product avoid contact with eyes. Wash hands completely after each use. If swallowed seek medical assistance immediately or contact poison control. If you are pregnant or nursing, seek the advice of your doctor before using this product.

Directions for use

Apply cream to sore muscles and joints and massage into skin as needed. For adults and children 2 years of age and older apply to affected area not more than 3 to 4 times daily. Children under 2 years of age consult a doctor.

Water, Dimethyl Sulfone, Clove bud oil, Peppermint oil, Eucalyptus oil, Aloe Vera, Ascorbic acid, Tocopherol, Glycine, Wintergreen oil, Jojoba oil, Arnica Montana Flower Extract, Polyacrylamide, C13-14 Isoparaffin, Laureth 7, Sodium Hydroxymethylglycinate, glycerol.



DRUG FACTS

ACTIVE INGREDIENTS

PURPOSE

Menthol (5%)----- External Analgesic

USES
For temporary relief of minor aches and pains of muscles such as: Simple Backache, Lumbago, Arthritis, Neuralgia, Strains, Bruises and Sprains.

FOR EXTERNAL USE ONLY - KEEP OUT OF REACH OF CHILDREN When using this product avoid contact with eyes. Wash hands completely after each use. Consult a doctor and discontinue use if conditions worsen or persist for more than 7 days. If swallowed, seek medical assistance immediately or contact Poison Control. If you are pregnant or nursing, seek the advice of your doctor before using this product.

DIRECTIONS FOR USE

Apply cream to sore muscles and joints and massage into skin as needed. For adults and children 2 years of age and older apply to affected area not more than 3 to 4 times daily. Children under 2 years of age consult a doctor.

DRUG FACTS (continued)

OTHER INGREDIENTS

Water, Dimethyl Sulfone, Clove Bud Oil, Eucalyptus Oil, Aloe Vera, Ascorbic Acid, Tocopherol, Glycine, Wintergreen Oil, Jojoba Oil, Arnica Montana Flower Extract, Polyacrylamide, C13-14 Isoparaffin, Laureth 7, Sodium Hydroxymethylglycinate, Glycerol

Made in the USA Distributed by Rejuventus, Inc. Chattanooga, TN 1-866-379-3510 www.reactice.com



Reactice Reactivating Ice Baume external analgesic 16 fl oz./473ml



16 fl oz./473ml

REACTICE REACTIVATING ICE BAUME

menthol cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75963-125
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	118.29 mL in 100 mL	

Inactive Ingredients			
Ingredient Name	Strength		
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)			
CLOVE (UNII: K48 IKT5321)			
PEPPERMINT OIL (UNII: AV092KU4JH)			
EUCALYPTUS OIL (UNII: 2R04ONI662)			
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)			
ASCORBIC ACID (UNII: PQ6CK8PD0R)			
TOCOPHEROL (UNII: R0ZB2556P8)			

GLYCINE (UNII: TE7660 XO1C)	
JOJOBA OIL (UNII: 724GKU717M)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
LAURETH-7 (UNII: Z95S6G8201)	
SO DIUM HYDRO XYMETHYLGLYCINATE (UNII: DIG6 BWZ9 XT)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:75963-125-01	118.29 mL in 1 JAR		
2 NDC:75963-125-02	473 mL in 1 JAR		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	07/21/2011	

Labeler - Rejuventus, Inc. (032186703)

Registrant - Rejuventus, Inc. (032186703)

Establishment			
Name	Address	ID/FEI	Business Operations
Rwm Technologies		003215779	manufacture

Revised: 1/2012 Rejuventus, Inc.